PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : G06F — A2

(11) International Publication Number: **WO 98/50840**

(43) International Publication Date: 12 November 1998 (12.11.98)

(21) International Application Number: PCT/US98/09490

(22) International Filing Date: 8 May 1998 (08.05.98)

(30) Priority Data:
08/852,958 8 May 1997 (08.05.97) US

(71) Applicant: PINNACLE INTELLECTUAL PROPERTY SERVICES–INTERNATIONAL, INC. [US/US]; Suite 260, 2030 East Flamingo Road, Paradise Valley, NV 89119 (US).

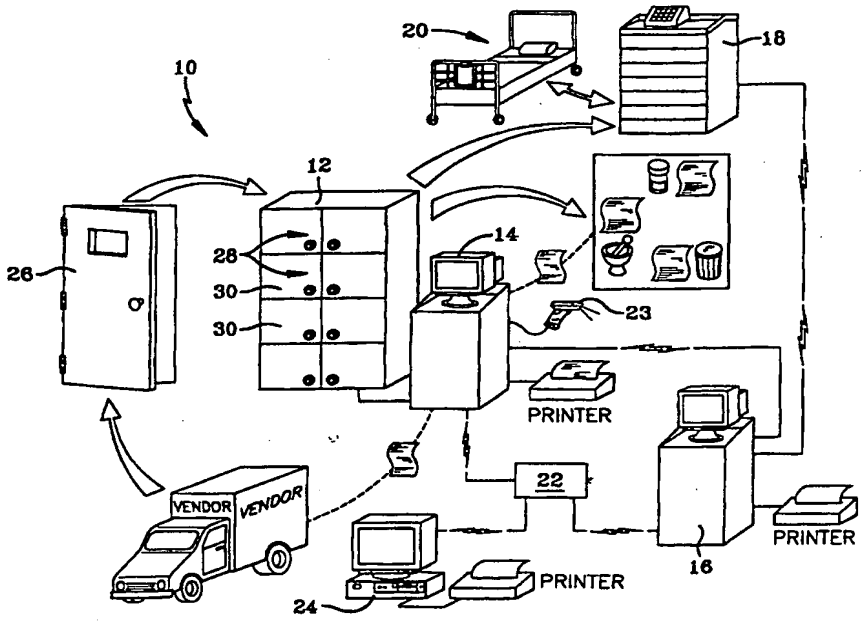
(72) Inventors: KING, James, H.; 1627 Winsome Drive, Escondido, CA 92029 (US). SALOOM, George, T.; 100 South Broadway, Scottsdale, PA 15683 (US).

(74) Agent: STEFFENSMEIER, Michael, D.; Cardinal Health, Inc., 5555 Glendon Court, Dublin, OH 43016 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: SYSTEM FOR THE DISTRIBUTION OF NARCOTICS



(57) Abstract

A drug distribution system is described in which narcotics are tracked from the time they are delivered to a health care facility to the time they are administered to patients. A locked vault accessible only through logging on to a computer software system records drugs withdrawn and by whom. An inventory and purchase order system are available with the invention.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

SYSTEM FOR THE DISTRIBUTION OF NARCOTICS

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates generally to a system for the distribution of narcotics by health care providers, and more particularly, is related to an electronic, computerized drug information system that assists a health care provider in tracking drug distribution at the health care provider facility.

Current trends in Controlled Substance Regulations were most influenced by the creation of the Bureau of Narcotics and Dangerous Drugs (BNDD) and the adoption of the Controlled Substance Act (CSA) of 1970. This Act established the rules and regulations regarding handling, distribution and control of substances of abuse. The BNDD was the governing body of the Federal government for the enforcement of these rules and regulations. The CSA provided for the following:

a) The creation of the 5 Schedule model for the classification of controlled substances with Class 1 (CI) having the highest potential for abuse, to Class 5 (CV) having the lowest abuse or addictive potential. The classes are outlined below.

Class Schedule 1 (CI) meet this criteria:

Have no currently accepted medical use in the United States

Have the highest potential for abuse.

Have a lack of safety for use even under medical supervision.

Examples: Heroin, L.S.D.

Class Schedule 2 (CII) meet this criteria:

Have a currently accepted medical use in the United States.

Have the highest potential for abuse.

Abuse of medication or substance may lead to severe psychological or physical dependence.

Example: Cocaine, Morphine, Percocet

Class Schedule 3 (CIII) meet this criteria:

Have a currently accepted medical use in the United States.

Have a potential for abuse less than substances in CI or CII.

Abuse of the drug may lead to moderate or low physical dependence or high psychological dependence.

Example: Tylenol with Codeine, Vicodin, Anabolic Steroids

Class Schedule 4 (CIV) meet the following criteria:

Have a currently accepted medical use in the United States

Have a low potential for abuse relative to substances controlled in CIII.

Abuse of the drug may lead to limited physical dependence or psychological dependence, relative to substances controlled in CIII.

Example: Valium, Halcion

Class Schedule 5 (CV) meet the following criteria;

Have a currently accepted medical use in the United States.

Have a low potential for abuse relative to drugs controlled in CIV.

Abuse of the drug may lead to limited physical dependence or psychological dependence, relative to substances in CIV.

Example Robitussin with Codeine Elixir

b) Virtually every person who legitimately handled controlled substances was subject to regulation by the BNDD. Entities subject to direct regulation through licensing (registration) by the BNDD were hospitals, pharmacies, pharmacists, researchers, drug manufacturers, drug distributors, physicians, nurses and many others.

In 1973, the BNDD was abolished. Its responsibilities were inherited by its successor, the Drug Enforcement Agency (D.E.A.). The D.E.A. reports directly to the FBI and has two missions. One is law enforcement, and the other is regulating the handling of controlled substances. This was the first time that the FBI was given a clearly defined role in federal drug law enforcement.

Controlled Substance Regulation Time-Line:

1968 ----------	BNDD formed by President Nixon
1970 ----------	Controlled Substance Act was signed The Schedule model for controlled substance classification was established
1973 ----------	BNDD was abolished and D.E.A. was formed FBI given a role in drug law enforcement
1978 ----------	Pyschotropic Substances Act was signed
1984 ----------	CSA was amended to allow expedited scheduling of substances posing public health hazard
1986 ----------	Controlled substance analogs to be placed in schedule CI
1988 ----------	D.E.A. now regulated precursor chemicals
1990 ----------	Anabolic Steroids added to D.E.A. control as CIII

Law enforcement handles the illicit aspects of the control of substances of abuse. The regulatory responsibilities of the D.E.A. focus on the control of legitimate

handlers of controlled substances, equipment and raw materials used to make them. Prevention of such articles from being diverted into illicit channels is the primary goal of this regulation. The D.E.A. shares its regulatory authority with the State Boards of Pharmacy in each state. The D.E.A.'s power of enforcement is through the imposition of fines or incarceration. The State Board of Pharmacy's power of enforcement is through the ability to revoke privileges or licenses of individuals. The regulations established by the D.E.A and State Boards of Pharmacy directly influences legitimate controlled substance distribution.

The software of the present invention is named C^{II}Safe. This name comes from the controlled substance classifications. Class CII has the highest abuse potential and is recognized as a class which requires close monitoring. However, C^{II}Safe is equally applicable to the other classifications. Another component of the present invention is a narcotic vault. Hospital pharmacies have traditionally included a locked narcotics vault with limited access to authorized personnel. The present invention is adapted to electronically communicate with a latch on the door of a narcotics vault. The present invention may also be adapted to electronically communicate with a free standing commercially available multi-compartment narcotics vault. In one embodiment of the present invention an eight door narcotics vault is electronically connected to the C^{II}Safe computer which enables the C^{II}Safe computer to control the unlocking of individual doors of the vault.

The present invention works in communication with a computer console that may be located in a hospital pharmacy, for example. The hospital pharmacy console

processor may be arranged in a network configuration to communicate with one or more automatic medicine dispenser units, sometimes referred to as medstations, which are typically located at nursing stations on each floor of a hospital.

A further component may be needed for communication to be established between the pharmacy console and the C^{II}Safe computer. This processor interface unit has been referred to by the present inventors as Procar. Finally, Procar may be electronically connected to a drug vendors computer system for sending and receiving related messages.

The system components, including the locked vault, C^{II}Safe, Procar, the pharmacy console, and the various medstations, all in electronic communication, is believed to be unique.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a diagrammatical view of a preferred embodiment of the system of the present invention;

Figure 2 is a flow chart of a preferred embodiment of the system of the present invention;

Figure 3 is a diagrammatical view of a communications link between the C^{II} Safe computer, the interface computer, and the pharmacy console computer of the present invention;

Figure 4 shows an example of a Controlled Drug Administration Record;

Figure 5 shows an example of a 24 Hour Controlled Substance Record;

Figure 6 shows an example of an Anesthesia Controlled Substance Sheet;

Figure 7A shows an example of an Expire Waste or Recall Transaction Record;

Figure 7B shows an example of the packaging is association with the record of Figure 7A;

Figure 8A shows an example of barcode labels on various medications;

Figure 8B shows an example of a label for a particular medication; and

Figure 9 shows a diagrammatical representation showing audit, intervention and reporting of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT(S)

Referring now to the drawings, there is shown in Figure 1 a preferred embodiment of the system of the present invention. The system 10, includes a narcotics vault 12 in communication with a data processor 14 which is adapted to run the C^{II}Safe program. A pharmacy console data processor 16 is in electronic communication with one or more medstations 18 located at nursing stations 20 at various wings of the hospital.

To facilitate communication between the C^{II}Safe data processor 14 and the pharmacy console processor 16 an interface computer 22 is provided and is electronic communication with both data processors 14, 16. A vendor 24 may have a computer in communication with the interface computer 22. The vendor computer 24 may receive electronic purchase orders from the interface computer 22 and respond with an electronic acknowledgment of receipt of a purchase order. Upon confirming receipt of

a drug purchase order, the vendor may ship the requested quantities of drugs to the health care provider making the purchase order. The drugs are received by the health care provider 26 and are later recorded and placed in the locked vault 12. The vault 12 may have multiple compartments 28 accessible through individual doors 30. The doors 30 may be equipped with electronic latches controlled by the C^{II}Safe computer 14. The C^{II}Safe computer may be configured to prevent access by individuals who do not enter an authorized personnel identification number. Once a health care provider has successfully entered the C^{II}Safe software the computer 14 will prompt the user to enter various information concerning the drug or drugs needed from the vault and the person making the request to access the vault. If the transaction request is accepted, in a preferred embodiment of the invention only the door or doors necessary to be opened to access the particular requested drugs will open while the other doors to the narcotics vault will remain locked. When a user has removed any drugs from the vault the user is then prompted by the C^{II}Safe computer 14 to enter the type of drug removed from the vault and the quantity removed. The user may be prompted to enter a count of the drugs remaining in that compartment of the vault.

Once drugs are removed from the locked vault they are taken to the various medstations 18 and loaded into preassigned compartments in the medstations. When a nurse accesses a medstation and removes a drug to administer to a patient, the medstation may refuse access to the nurse unless proper identification is entered into the medstation 18. The medstation may prompt the user to enter the nursing station location, patient identification, nurse identification, optional witness identification (who

witnesses the nurse removing the drugs from the medstation), requested drug identification, and actual drug count removed from the medstation. All of this information may be electronically relayed to the pharmacy console 16 through the interface computer 22 to the C[II]Safe computer 14. This information may be used by C[II]Safe to determine when additional drugs need to be purchased to keep drug supplies above a threshold value.

For example, if a predetermined threshold quantity of a particular drug supply is set at 100 tablets for each medstation, C[II]Safe will prompt the user if and when the number of tablets at each medstation drops below 100. The system of the present invention may be configured in a number of ways to automatically place purchase orders with drug vendors when predetermined threshold quantity levels are experienced. This aspect of the invention eliminates much of the conventional handwritten purchase orders and handwritten inventory procedures that have been in place at hospitals for many years. With each medstation reporting the quantity and identification of drugs removed, to the pharmacy computer and the C[II]Safe computer, hospitals now have, with the present invention, the capability of just in time inventory control of medicines in supply at the hospital.

When drugs are received by the hospital they may be bar coded upon receipt, or they may be bar coded by the drug supplier prior to shipment. In either event, bar coding of drug packaging may be useful to hospital technicians in entering drugs at the vault. Instead of manually typing in each drug received at the pharmacy console or C[II]Safe computer, a commercially available bar code scanning device 23 may be used

to gather the needed drug information (i.e., drug type, quantity, expiration date, destination, etc.).

Use of a stand alone narcotics vault is preferred since it offers a greater degree of control over drug withdrawals from the vault. One such stand alone vault is commercially available from the Pyxis Corporation in San Diego, California, the assignee of the present invention. The terminology "stand alone" is intended to mean that the unit is not physically built into a hospital room as conventional vaults are installed. The term "stand alone" is not intended to mean that it has no connections to it; in fact it is important to the present invention that the vault be connected electronically to an operating computer such as the C^{II}Safe computer. With a vault as provided by Pyxis Corporation, different drugs may be housed in different compartments of the vault with each compartment having its own access door which is independently operable from all other doors in the vault. Thus, if a hospital employee is only given authorization to access certain drugs in the vault, that employee's personal identification number may be entered into the C^{II}Safe computer memory so that the computer will only actuate those doors of the vault that offer access to the drugs that employee is authorized to access. Other doors, protecting drugs not to be accessed by that employee, will not open with that employee's personal identification number.

Furthermore, C^{II}Safe will provide a data trail tracking each person who accesses the vault and recording what drugs each person removed. A user cannot physically access the vault without first entering the user's personal identification code or PIN number. While it is incumbent on the user to record what was removed by entering this

data via the keyboard or keypad at the computer connected to the vault, the user may also be required to enter a count of the quantity of drug still in that compartment of the vault just accessed. In this manner it would be very difficult for any one individual to take more drugs from the vault than that individual has recorded at the computer.

Drug tracking with the present invention occurs at each of the following steps:

1. incoming purchases from the drug wholesaler to the health care provider pharmacy;
2. from pharmacy to nursing station;
3. from pharmacy to out-patient;
4. from pharmacy to IV Room to be compounded then back to pharmacy as new product;
5. from pharmacy to expired or waste status;
6. from pharmacy back to wholesaler or manufacturer as recalled product;
7. from pharmacy to secured inaccessible inventory;
8. from pharmacy to an outside pharmacy.

The system of the present invention operates in real time and stores data for an extended number of years for quick reporting of drug distribution at the health care facility for a given period of time. The system may also be used to flag drug distribution counts that exceed a predetermined norm. For example, if a report indicates that one particular employee is removing drugs in substantially greater quantities than other employees similarly situated, the system reports will note this abnormal behavior for further review by administrators.

In effect, the system of the present invention closes the loop of drug distribution at health care providers. The present invention enables users to track a drug from the delivery truck into the pharmacy vault, to the nursing station medstations, and ultimately to administration to each patient. Such a complete closed loop system has heretofore not been available.

When a nurse removes a drug at a medstation, an electronic message of that drug removal is sent to the C^{II}Safe computer and is used therein for many functions including inventory tracking and reorders. If a nurse removes a drug from a medstation and the patient refuses to accept the drug the nurse may return the drug to a "return to bin" area within the medstation and the nurse records this information into the medstation computer. At a future time, a technician will remove the drugs from the "return to bin" area and return the drugs to the vault. At the vault, the technician must enter the drug types and quantities of each that are being returned to the vault. If the drug types and quantities entered at the vault C^{II}Safe computer by the technician do not match the information previously received by the C^{II}Safe computer from the medstations, a report printed by the C^{II}Safe computer will indicate this discrepancy for an administrator to review.

Figure 2 shows a flow chart and Figure 3 shows a diagram of a communications link between various components of this embodiment of the invention. It is to be recognized that the Procar interface computer is a part of this embodiment in order to facilitate communications between C^{II}Safe and existing console software at the pharmacy computer. It is to be recognized that other embodiments of the present

invention may incorporate matching protocols at the console and C[II]Safe to avoid use of a proper interface.

Figure 4 shows an example of a printing of controlled drug administration records (CDAR), another record form useful in the present invention. Laser printed CDAR's are generated for non-MedStation areas. These unit-specific records can also be utilized by ancillary areas that may only stock one or two controlled substances. Each sheet is serialized and barcoded to prevent counterfeiting.

Figure 5 is another form of CDAR that C[II] Safe is capable of printing. Be aware that Control Drug Administration Records will be called many different names. Some example names are: CDAR, CSAR, Day Sheet, 24 hour sheet, Single Sheet, Shingle Sheet, Perpetual count sheet and Dispensation Record.

Figure 6 shows a form for controlled substances documentation for each kit for an automated means for controlling the traditional OR/Anesthesiology Kit process. This form allows for the creation of various types of kits and tracks their assigned inventory. It prints a controlled substance documentation form for each kit. Kits can be case or user specific.

Figure 7A may be used when a pharmacy encounters broken, outdated or otherwise unusable controlled substances. These items remain part of the vault inventory until destroyed, but destruction normally takes place with D.E.A. authorization on 1-2 times per year. This often makes vault reconciliation more confusing. C[II]Safe allows assignment of medications to a "pending destruction" status

to automatically keep track of these unusable items. Figure 7B shows an example of a waste deposal packet for medications.

Figure 8A shows an example of barcode labels on medication. Manufacturer's barcodes can be scanned to identify medications in C^{II}Safe. C^{II}Safe can generate its own barcode label if no manufacturers' barcode is available. In C^{II}Safe, barcodes are especially effective in tracking the controlled substance transactions occurring outside of the medstations. Figure 8B is an example of a label for a particular medication.

Figure 9 represents a diagrammatical view of the forms used during the controlled distribution process. In the hospital setting, the pharmacy is the cornerstone of the controlled substance distribution process. Controlled substances remain under pharmacy domain from the time a vendor shipment is received until the medications are administered to the patient. This diagram outlines the controlled substance distribution process. Effective audit trails are mandatory for each distribution area. Federal law requires that records for controlled substances be accurate and readily retrievable for a period of not less than two (2) years. Most State Boards of Pharmacy have chosen to make this requirement more stringent and mandate that these records be readily retrievable for five (5) years. The fine for inaccurate or incomplete record keeping is $25,000 per line item. A line item is one medication, i.e., Morphine 15 mg tablet. If the controlled substance records for a medication are inaccurate by one dose or one thousand doses, the fine is still $25,000. With the average pharmacy stocking 100 to 250 different controlled substances (line items) in its inventory, the hospital is potentially at risk for $2,500,000 to $6,000,000 if audited.

The D.E.A. and State Boards of Pharmacy are continually monitoring the health care continuum for possible diversion or misuse of controlled substances by performing routine reviews. The routine audits do not usually result in the imposition of fines. Fines and severe regulatory measures occur only if the D.E.A. or State Board uncover gross negligence or have reason to believe that diversion is occurring in which case a thorough audit ensues.

The D.E.A. performs many of its monitoring functions via various forms and reports that every hospital is required to submit. These forms include D.E.A. Form 222, D.E.A. Form 41, D.E.A. Form 106 and the Biennial Inventory Report.

Several diagrams are included herewith to better explain the invention.

True just in time inventory

C[II]Safe's suggested order function eliminates the need to "walk the shelves" by listing medications which have fallen below the par days supply set by the user. This report, listed below as Table 1, is based on the previous 90 days of utilization (more heavily weighted towards the last 10 days to catch utilization spikes). The order report will provide NDC numbers, vendor order numbers and suggested order quantities. This report separates schedule II medications from other medications.

TABLE 1

SUGGESTED MEDICAL ORDER REPORT

C[II]SAFE-NV
Prepared Date: 01-01-97 Time: 21:39:20

TRAN. CHECK : 770 C[II]Safe Software v4.0 DAYS CHECKED : 34

DRUG	ITEM	CUR PHY	WEEK(S) UTILIZATION 1	2	3	4	TOT. USED	WKS. SUP.	SUG. ORDER
ACETAMINOPHEN w/COD ELIX SML	17	96	132	264	395	527	640	1	92
N.D.C. 00364760905 EACH $ 0.45 ALL $ 41.40 ORDER NUMBER : 857-645 PACKAGE SIZE : PAR DAYS: 10									
ACETAMINOPHEN w/CODEINE 60 MG	72	8	206	412	618	824	1001	0	286
N.D.C. 00364786501 EACH $ 0.02 ALL $ 5.43 ORDER NUMBER : 540-091 PACKAGE SIZE : PAR DAYS: 10									
DIAZEPAM 5 MG TAB 1 PACKET	92	15	105	210	315	420	510	0	135
N.D.C. 54634187965 EACH $ 0.02 ALL $ 2.97 ORDER NUMBER : 509-001 PACKAGE SIZE : PAR DAYS: 10									
LORAZEPAM 0.5 MG TAB	97	22	24	49	73	97	118	1	13
N.D.C. 00364615466 EACH $ 0.02 ALL $ 0.19 ORDER NUMBER : 763-922 PACKAGE SIZE : PAR DAYS: 10									

Value of This Order: $ 241.92

This report allows the user to predict drug utilization and increase inventory turnover. N.D.C. and schedule II separation provides all information needed to complete D.E.A. Form 222.

Streamline Pick and Delivery for MedStations

Table 2A represents data that can be generated for batch pick lists which decreases the number of pharmacy transactions and streamlines the refill process. Refill quantities are brought to the screen for the editing process and with one keystroke, they are automatically deducted from the C^{II}Safe active inventory.

TABLE 2A

PHARMACY PREVIEW

C^{II}SAFE-NV
Prepared Date: 04-21-1997 Time: 23:52:07

MED NAME	SUGGESTED PULL	Safe Balance BEFORE	AFTER	ACTUAL
ACETAMINOPHEN w/COD ELIX BLK	480	360	480	_____
ACETAMINOPHEN w/CODEINE 30 MG	20	315	295	_____
CHLORAL HYDRATE 500 MG SYRYUP	41	480	430	_____
COCAINE 4% SOLUTION (ML)	4	6	2	_____
CODEINE PHOSPHATE 15 MG/5ML	15	64	49	_____

C^{II}SAFE v4.0 TOTAL ITEMS: 5 PAGE NO.:

1

TABLE 2B

DRUG	UNIT	PAR	ON UNIT	SENDING	CHANGE TO
MORPHINE INJ 2 MG SYRINGE	IMU	10	10	10	
MORPHINE INJ 4 MG SYRINGE	IMU	10	7	10	
MORPHINE INJ 10 MG SYRINGE	IMU	10	7	10	

USE THE ↑↓ ARROW KEYS TO MOVE TO DRUG, THEN TYPE ANY CHANGE IN QUANTITY NEEDED

Reconciling Vault Issues/Returns for Medstations

Table 3 depicts a chart that will indicate transactions that must be manually located. C^{II}Safe will automatically track medications that have been removed from stock to be issued to a medstation and reconciles these issues with medstation replenishment transactions. The same is true for unload transactions being returned to the vault. C^{II}Safe reports notify the pharmacy of outstanding transactions in either system.

TABLE 3

TRANSACTIONS THAT MUST BE MANUALLY LOCATED

C^{II}SAFE-NV
Prepared Date: 04-23-1997 Time: 16:14:20

TRANSACTIONS ENTERED IN THE MEDSTATION BUT NOT ENTERED IN C^{II}SAFE

ED1	MORPHINE 10 MG TUBEX	20	01384	LOADED
SICU	PCA-IV MORPHINE SULP (ADDVNT)	10	11151	LOADED
BICU	NARCOTIC DRIP (FOR MEDSTATION) OT 1	10626	LOADED	
ED1	KETAMINE 100 MG/ML INJ SML VI	4	04711	LOADED
ED1	MEPERIDINE HCL 50 MG INJ 1ML	10	01300	LOADED

Single-Point Controlled Substance Reporting

Table 4 shows that C^{II}Safe tracks all areas of controlled substance migration from the point of purchase to removal for patient administration. C^{II}Safe can provide reports for any MedStation transaction, any controlled substance, or any user for any time frame queried.

TABLE 4

C^{II}SAFE-NV

STATION	QTY.	DESCRIP.	DRUG NAME	CLASS	PATIENT NAME	USER NAME	USER ID	DATE	TIME
7E	1	LOADED	NARCOTIC DRIP	2		CABUANG, WILMA	WC	08-01-96	09:03:28
BICU	10	LOADED	MORPHINE 10 MG TUBEX	2		STEPHENS, RHONDA	RX RMS	08-01-96	09:24:04
B1MU	10	LOADED	MEPERIDINE HCL 50 MG 1MJ 1ML BY	2		STEPHENS, RHONDA	RX RMS	08-01-96	09:25:30
BIMU	10	LOADED	MORPHINE 10 MG TUBEX	2		STEPHENS, RHONDA	RX RMS	08-01-96	09:25:55

Total transactions: 4
Sum of all Trans: 258

Proactive Diversion Tracking Report

Table 5 shows a proactive diversion tracking report which allows comparison of transactions per day by a given user listed by medication and by nursing station. All usage falling above the norm by 2 standards of deviation (+2 std. deviations) or more will be flagged.

TABLE 5

Med: Percocet Tab - 1 packet Interface #03706 STA: 4E Month:

NAME	I.D.	DOSES	DAYS	DOSES/DAY
Santos, Gloria	GASF	35	10	3.5
Devera, Ofelia	OMD	34	7	4.857143
Generas, N. Teresa	NTG	19	3	6.333333
Reed, Gwendolyn	GBR	16	2	8
Padilla, Estrella	EGP	42	6	7

Med: Percocet Tab - 1 packet Interface #03706 STA: 4E Month

Total Transactions:
Sum of Matching Transactions:
Total User Days:

Sum of Accesses per Day:
Sum of the Squares of Accesses per Day:
Total Users:
Mean:
Standard Deviation:

All activity 2 standard deviations above the Mean

Transactions To/From Other Pharmacies

Table 6 shows that, in urgent situations, pharmacies may loan to or borrow items from another local pharmacy. In some cases, such as for schedule II drugs, these transactions may involve an actual sale or purchase of the item and exchange of a DEA-222 form. Some states may not allow this. (i.e., California does not allow transfer of C^{II}'s between pharmacies). C^{II}Safe records and tracks these transactions along with DEA-222 information. C^{II}Safe will generate both a sender's copy, as shown below in Table 6, and receiver's copy of the transaction.

TABLE 6

MEDICATION SALE TO OUTSIDE PHARMACY

C[II]SAFE-NV
Prepared Date: 04-22-1997 Time: 23:57:15

OUR PHARMACY DEA NUMBER:_____

QTY # 25
DRUG: PERCOCET TAB 1 PACKET
REF. # S0471

PHARMACY SOLD TO: BAPTIST HOSPITAL

THEIR PHARMACY DEA NUMBER:_____

STREET ADDRESS:_____

CITY, STATE, ZIP:_____

SIG. OF RECEIVER:_____

DATE SOLD: 04-22-1997
PHARMACIST: SAM DEA-222 ORDER NO.: 99999999

SENDER'S COPY! SAVE AT SITE
V/1616

Fill Prescription Function

Table 7 shows a Prescription Pick-Up Receipt in which C[II]Safe generates labels and keeps records for outpatient dispensing of controlled substances for take home medications, pass medications, after hours emergency prescriptions and employee prescriptions. Labels meet regulatory requirements, however, the user does have the option to continue to utilize current system labels. Dispensed amounts are automatically deducted from vault inventory.

TABLE 7

PRESCRIPTION PICK-UP RECEIPT

C^{II}SAFE-NV
Prepared Date: 04-23-1997 Time: 12:19:31

QTY # 20
DRUG: ALPRAZOLAM 0.5 MG TAB 1 PACKET
REF. # 1091

PATIENT NAME: FEENEY, ROBERT

PHYSICIAN: LEE

DATED FILLED: 04-23-1997

PHARMACIST: SAM DATE PICKED UP: _____/_____/_____

SIG. OF DISPENSING R. Ph. :

_____

SIG. OF RECEIVER :

_____

Drug Stock Movement

Table 8 shows that C^{II}Safe will maintain transaction records for two stocks. An area designated for storage of large volumes may be maintained separately from the working stock. Medications may be easily transferred between stocks as a separate transaction or during receiving shipments and dispensing medications to the nursing stations.

TABLE 8

DRUG STOCK MOVEMENT RECORD

C^{II}SAFE-NV
Prepared Date: 04-21-1997 Time: 20:57:29

MED NAME	QTY	MOVE TO	SEC. BAL.	ACC. BAL.
Alfentamil 6 ml AMP	100	accessable	100	41
Cocaine 4% solution 4 ml	20	accessable	20	4
Codeine 30 mg bulk tab 100	500	accessable	500	300
Codeine 60 mg bulk tab 100	1000	accessable	1000	200

Total Medications to be Moved: 4

Compounding with Controlled Substances

As shown in Table 9, C^{II}Safe will also allow the pharmacy to define line items which are compounded rather than purchased from suppliers. A ratio is established between the manufactured product and the number of units of the compounded item which can be prepared. When a manufactured drug is removed for compounding, C^{II}Safe automatically transfers the controlled drug inventory from the original line item to the compounded line item. Even a method for accounting for manufacturer overfill is provided in tracking this inventory.

TABLE 9

COMPOUNDING/ADD-MIXTURE RECORD

C[II]SAFE-NV
Prepared Date: 04-22-1997 Time: 13:31:44

TRANSACTION NUMBER: 047008 DATE: 04-22-1997

DRUG USED: ACETAMINOPHEN W. COD ELIX BLK LINK : 196

MANUFACT:

VAULT BAL.: 480

QTY BEING USED: 480 LOT: EXP.

____/____/____

CALCULATED AMOUNT OF WASTE: _____

VARIANCE DUE TO OVER or UNDER FILL: _____
(Do not return variance to stock)

TOTAL AMOUNT WASTED: _____

DRUG BEING MADE: ACETAMINOPHEN W/COD ELIX 5ML LINK : 17
VAULT BAL.: 192
QTY BEING MADE: 96 EXP: ___/___/___ (or) IN 12 MONTHS

SAMPLE LABEL

COMPOUND PERFORMED BY: (sig.)_____

INSPECTED AND VERIFIED BY: (sig)_____

PAGE INTENTIONALLY LEFT BLANK

Reconcile Vault Inventory

Shown in Table 10 is a Controlled Substance Reconciliation Report for vault inventory verification that breaks out accessible inventory from secured inventory.

TABLE 10

CONTROLLED SUBSTANCE RECONCILIATION REPORT

C^{II}SAFE-NV
Prepared Date: 04-21-1997 Time: 21:00:26

Schedule II Auditor's

SIG:_____

ALFENTANIL 5ML AMP		4/21 REF:	FORM: INJ	PHYSICAL
COUNT:_____				
LOCATION:	ITEMS: 124	SCHEDULE II	SECURED: 100	ACCESSIBLE: 41
AMOBARBITAL 500MG VIAL		07/29 REF:	FORM: INJ	PHYSICAL
COUNT:_____				
LOCATION:	ITEMS: 134	SCHEDULE II	SECURED: 0	ACCESSIBLE: 4
BELLADONNA & OPIUM NO. 16A 6		08/09 REF: 00161	FORM: SUP	PHYSICAL
COUNT:_____				
LOCATION:	ITEMS: 34	SCHEDULE II	SECURED: 0	ACCESSIBLE: 53

C^{II}SAFE v4.0

Page 1

Financial Reports

As represented by Table 11, C^{II}Safe can store cost information for each medication. This allows for current inventory dollars values by medstation and the value of all stock in the medstations throughout the hospital. This results in extensive time savings during the annual pharmacy inventory.

TABLE 11

Single Drug Hospital Wide

INVENTORY SUMMARY

PERCOCET TAB 1 PACKET D.E.A. CLASS 2

WWP	15
SICU	21
MICU	25
IMU	38
ED1	11
BIMU	34
BICU	94
7W	113
7E	84
6W	16
6E	52
5IMU	23
4E	115
20B	25
11W	65
11E	92
10E	61
8W	50
CDA LOCKER	100
UCARE	15
PACU/SICU	25

SUB TOTAL OF UNITS:	1084	VALUE OF DRUG ON UNITS	$ 1073.16
AMOUNT IN PHARMACY	7335	VALUE OF DRUG IN PHY.	$ 7261.65
HOSPITAL WIDE TOTAL	8419	HOSPITAL WIDE VALUE	$ 8334.81

Page 1

D.E.A. Form 222

Whenever a hospital needs to reorder C^{II} narcotics, the pharmacist in charge must complete a D.E.A. Form 222 in triplicate. Fields to be completed on this form include: the name and address of the vendor through which the medications will be supplied, the name and National Drug Code (NDC) of each medication to be ordered, the quantity requested, the hospital's name, address and D.E.A. registration number and the signature of the pharmacy supervisor. Two copies of this form are mailed to the vendor, one copy remains at the hospital. The vendor fills the order and sends one copy of Form 222 to the D.E.A. The D.E.A. reviews these forms in order to detect excessive amounts of controlled substances being ordered by pharmacists.

C^{II}Safe-NV, through its Suggested Order Report, will provide a separate list of schedule C^{II} controlled substances that the hospital needs to order. This report provides: medication name, NDC number, vendor's item number and the quantity of medication the pharmacy should order based on utilization. By providing this information, C^{II}Safe-NV eliminates the need for the pharmacist to look up the NDC number in the order catalog, on microfiche or to walk to the shelf to check the numbers on a medication label.

D.E.A. Form 41

Another form, D.E.A. Form 41, must be completed by a hospital to record the destruction of outdated or unusable controlled substances. The pharmacy must submit this form requesting authorization to destroy a controlled substance medication in the

pharmacy. The D.E.A. reviews the Form 41 and sends notification of its approval to dispose of these items on a specific day. The pharmacy must destroy the medications and complete all appropriate documentation. In order to ensure that diversion does not occur, the D.E.A. may appear, without notice, to witness the destruction. It is for this reason that approval prior to destruction must be requested using Form 41.

C^{II}Safe-NV has an Expired Waste and Recall function in which all medications "pending destruction" are recorded. C^{II}Safe-NV can print reports listing all medications and quantities that need to be destroyed. This report makes the D.E.A. Form 41 simple to complete.

D.E.A. Form 106

Form 106 must be submitted to the D.E.A. when a hospital experiences theft or loss of any controlled substance. Missing controlled substances are most often discovered during an inventory verification. Pharmacies usually perform a physical count of all controlled substances every 14 to 30 days in order to reconcile their book counts to the actual inventory. Nursing usually performs an equivalent process every 8 to 24 hours. When a variance is discovered, extreme measures are taken to locate and resolve the discrepancy. In the event that the discrepancy remains unresolved, the pharmacy is then required to submit a Form 106. Filing this form indicates point toward diversion or inadequate record keeping procedures. It alerts the D.E.A. to the unresolved discrepancy and may lead to an extensive audit.

C^{II}Safe-NV was designed at a hospital which had experienced fines as a result of incomplete record keeping. It is designed to put processes in place which will eliminate lost doses from occurring. When used correctly, C^{II}Safe software combined with Narc Vault hardware closes the loop for each dose of each controlled substance which is received or dispensed by the pharmacy. By incorporating this form at the nursing station level, each dose of each controlled substance can be tracked from the time it is received from the wholesaler to the time it is removed to be administered to the patient.

Biennial Inventory Report

While it is common to perform physical counts every 14 to 30 days, Federal Regulations require a hospital wide inventory every two years (Biennial Inventory Report). Submission of the biennial inventory report provides the D.E.A. with an initial inventory level for auditing purposes and evidence of excessive supplies of controlled substances.

This report is on record with the D.E.A. and subsequently it cannot be altered to conceal diversion or inappropriate record keeping. The format and date of the biennial inventory are specific. Counts include inventory in the pharmacy, on the nursing stations and in any department that does not have its own D.E.A. registration number.

Biennial Schedule C^{II} medication inventories must be exact in count. Biennial Schedule C^{III} through Schedule C^{V} medication inventories are visual estimates. Even though the biennial Schedule C^{III} - C^{V} inventory is a visual estimate, records for all

controlled substance transactions must be exact. The difference in the regulations concerning biennial inventories and controlled substance transaction records leads to a false perception that the record keeping for Schedule C^{III} - C^{V} medications is less stringent than that of Schedule C^{II} medications.

Adding to this perception is the regional differences in the policies used by the D.E.A. to enforce and pursue compliance with the federal regulations. Many D.E.A. inspectors do not enforce exact count record keeping on Schedule C^{III} - C^{V} medications. This does not prevent substantial fines from future audits. When diversion or loss is reported, the D.E.A. often pursues compliance with regulations to the fullest extent. A hospital that has not tracked Schedule C^{III}-C^{V} medications in the past, may find it impossible to reconstruct transaction records, as required by law.

Performing a Biennial Inventory using manual methods can take several days. If the hospital has C^{II}Safe in the pharmacy and medstations on the nursing stations, this process is reduced to a matter of minutes.

Glossary of Terms

Accessible Stock	Working inventory staff utilizes (may be entire inventory)
Allocation	Dispense medication to a nursing unit
Acquisition	Receive medications from the wholesaler
ADM	Automated Dispensing Machine. (i.e. MedStations)
A.D.T.	Admission, Discharge and Transfer information usually provided by the pharmacy information system. A chemistry term referring to a chemical or substance that is structurally similar to another chemical or substance.
Analog	This similarity may also lead to a therapeutic similarity as well. Analogs can be modified chemically to produce the original chemical or substance.
Anesthesia Kit	Group of medications used either by procedure or anesthesiologist. Usually in individual lockable cases.
Asynchronous Communication	Type of communication used with interfaces. Transmission in which time intervals between transmitted characters may be of unequal length. Transmission is controlled by start and stop bits at the beginning and end of each character.
Audit Trail	Complete accountability for all controlled substances from receiving through patient administration.
Automatic ADM Restock	Function of C^{II}Safe-NV that suggests MedStation refill quantities to screen. User then edits and accepts.
Batched Signature Sheet	Receipt listing all medications that were issued to an individual location. Used to show proof of receipt and or delivery

Biennial Inventory	Hospital wide inventory of all controlled substances completed every other year and filed with the DEA.
B.N.D.D.	Bureau of Narcotics and Dangerous Drugs Precursor to the D.E.A.
C^{II}Safe-NV	The ultimate controlled substance tracking system. Combination of C^{II}Safe software with the NarcVault hardware.
C.D.A.R.	Controlled Drug Administration Record. A form used by non-automated nursing units for the purpose of recording patient administered doses of controlled substances. This form is either medication, unit or patient specific and may remain at the nursing unit until all doses dispensed with the form have been administered.
Closed Loop	Complete accountability for all controlled substances from receiving through administering to the patient.
Compounding/Add-Mixtures	The process by which one medication is transformed into another. Based on the compounding ratio set for the medication being made, the inventory levels of all medications will be adjusted. Example: Cocaine powder is removed from inventory to create T.A.C. Solution (Topically Applied Cocaine). The T.A.C. solution inventory will be increased while the cocaine inventory is reduced. Preparation of drips, PCAs and epidurals maybe performed under this function. Prepacking also may utilize this function.
Compounding ratio	The ratio set for compounding/add-mixtures function. Usually set to the smallest ratio available using whole numbers.

Controlled Substance	Medication in schedule C^{I}, C^{II}, C^{III}, C^{IV} or C^{V}. Any substance determined by the D.E.A. to have addictive or abuse potential. Substances in this category can cause severe to moderate psychological or physical dependence or are addictive in nature
C.S.A.	Control Substance Act of 1970. Created for the purpose of providing clear guidelines for controlled substance regulation. The CSA governs the actions of wholesalers, distributors, researchers, manufacturers, physicians, pharmacists, pharmacies, nurses and others who legitimately handle controlled substances.
C.S.A.R.	Controlled Substance Administration Record. See CDAR
Data Security interval	Amount of time between data backups.
Day Sheet	A form used by non-automated nursing units for the purpose of recording patient administered doses of controlled substances. Usually preprinted, the form lists the controlled substances which may be used by the unit. This sheet is replaced daily, primarily for billing purposes.
Default Quantity	Lowest quantity that a medication is dispensed in. usually the smallest package size.
D.E.A.	Drug Enforcement Agency. Charged with the federal regulation of controlled substances.
D.E.A. Form 41	A mandatory form to be completed and filed with the D.E.A. listing all controlled substances which have expired or are otherwise unusuable. Permission to destroy is granted by the D.E.A. after receipt.
D.E.A. Form 106	A mandatory form to be completed and filed with the D.E.A. listing any missing doses of controlled substances.

D.E.A. Form 222	A triplicate order form to be completed and filed with the wholesaler for replenishment of CII controlled substances. Wholesaler forwards third copy to D.E.A.
Delivery Signature Sheet	Receipt listing all medications that were issued to an individual location. Used to show proof of receipt and or delivery.
Deallocation	Return of medication from the nursing unit.
Diversion	Drugs being routed through inappropriate channels, i.e., theft.
Drip Sheet	A form used by nursing for the purpose of recording information regarding the administration of IV's.
Drug Class	Ranking by D.E.A. based on addiction and abuse potential
GPO	Group Purchasing Organization
Linkcode	Secondary C^{II}Safe-NV drug identification number
Lot Number	Internal number which the manufacturer assigns to each "batch" of product produced. If a problem is identified with a batch of product, the lot number is used to identify all product manufactured at the same time.
Map Location	Position in vault where medication is stored.
N.D.C.	National Drug Code
Null Modem Cable	Communication cable used for interface connection.
Par Days	Number of days supply to carry as inventory. Based on average use.
Perpetual Inventory	Running total of inventory.
Pharmacy Review	Report summarizing suggested medication refill quantities for ADMs. Allows user to verify quantities on hand prior to editing.

Pick list	Report summarizing medication refill quantities for ADMs. Used to pick medications from inventory by medication not transaction.
Precursor	A chemistry term used to describe a chemical or substance from which the controlled substance originates. Example: Substance A + Substance B = Substance C. Substances A and B are precursors to Substance C.
Readily Retrievable	Controlled substance records must be filed and stored on-site in such a manner as to be easily distinguishable from other non-controlled substance records. Many states mandate that CII records be filed separately from all other records. There must also be methods in place to accurately track each dose of each controlled substance during its life cycle in the hospital. Federal law mandates that controlled substance records be readily retrievable for a period of two (2) years. Most states have increased this requirement to 5 years.
RS232 Port	A standard serial communications port found on most PC's.
Scheduled Medications	Controlled substances.
Secured Stock	Excess inventory usually stored in secondary location.
Signature Sheet	Receipt filed for proof of transaction (i.e., delivery, sale prescription)
Shingle Sheet	A form used by non-automated nursing units for the purpose of recording patient administered doses of controlled substances. Easily recognizable by the multiple sub forms attached (shingles). This form is medication and/or patient specific and may remain at the nursing unit until all doses dispensed with the form have been administered. Shingles are used for billing purposes.

Shingle-less Sheet	Form generated by C^{II}Safe-NV resembling the layout of a shingle sheet. Used by non-automated nursing units for the purpose of recording patient administered doses of controlled substances.
Single Sheet	Administration record with one medication.
Suggested Purchase Order	Reorder function of C^{II}Safe-NV. Suggests quantities to reorder from wholesaler based on par day levels.
State Board of Pharmacy	Each state has a Board of Pharmacy which governs the licensing of Pharmacists practicing in that state. The State Board can revoke a pharmacist's privileges to handle controlled substances or in situations where abuse of these privileges is proven, can revoke the pharmacist's license.
Wedge Decoder	Device used between a laser scanner and the PC that converts scanned bar codes to key strokes.

The inventors herein have devised and reduced to practice a unique system for the distribution of narcotics that overcome the shortcomings of the systems currently in place at most medical institutions.

While the system and forms described herein constitutes a preferred embodiment of the invention, it is to be understood that the invention is not limited thereto, and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

1. A system for the distribution of narcotics at a health care facility, comprising:

a pharmacy computer adapted to record drug types and quantities administered to patients;

a locked drug vault adapted to house a plurality of drugs; and

an inventory computer in electronic communication with said pharmacy computer and said vault, such that said inventory computer receives information from said pharmacy computer concerning drugs administered to patients and said inventory computer controls access to said vault.

2. The system of claim 1, further comprising:

at least one automated medstation at a nursing station, said medstation adapted to store drugs in electronically actuated compartments, said medstation electronically connected to said pharmacy computer to send drug withdrawal information to said pharmacy computer.

3. The system of claim 1, wherein said inventory computer is adapted to provide real time inventory reports of drugs at said health care facility.

4. The system of claim 1, further comprising an automatic purchase order structure in electronic communication with a drug supplier to order drugs from said supplier when drug inventory levels reach predetermined threshold limits.

5. The system of claim 1, wherein drug types and quantities information are contained in bar codes attached to drug packaging.

6. The system of claim 5, further comprising at least one bar code scanner in electronic communication with said inventory computer.

7. A method of drug distribution, comprising the steps of:

providing a pharmacy computer adapted to record drug types and quantities;

providing a locked drug storage vault;

providing an inventory computer electronically connected to said pharmacy computer and said vault;

accessing the contents of said vault by entering a personal code into said inventory computer;

entering into said inventory computer the drug type and quantity withdrawn from said vault;

entering into said pharmacy computer the drug type and quantity administered to a patient;

reconciling the drug count withdrawn from said vault with the drug count administered to a patient.

8. The method of claim 7, further comprising the step of providing an automated medstation in communication with said pharmacy computer for storing drugs near patient locations.

9. The system of claim 7, wherein said inventory computer is adapted to provide printed reports of drug inventory and administration.

10. The system of claim 7, further comprising the step of automatically sending an electronic purchase order to a drug supplier when predetermined drug inventory levels are reached.

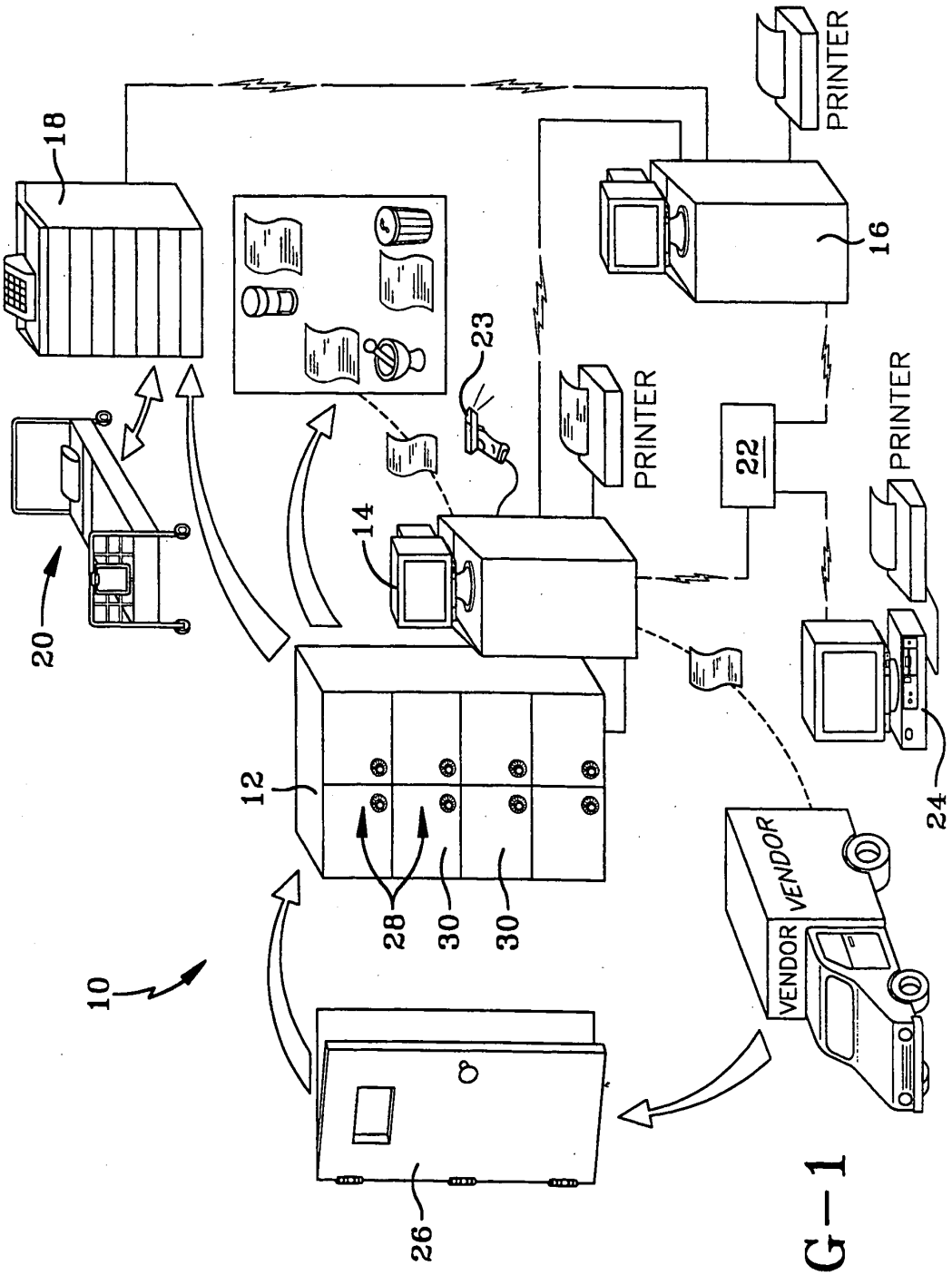


FIG-1

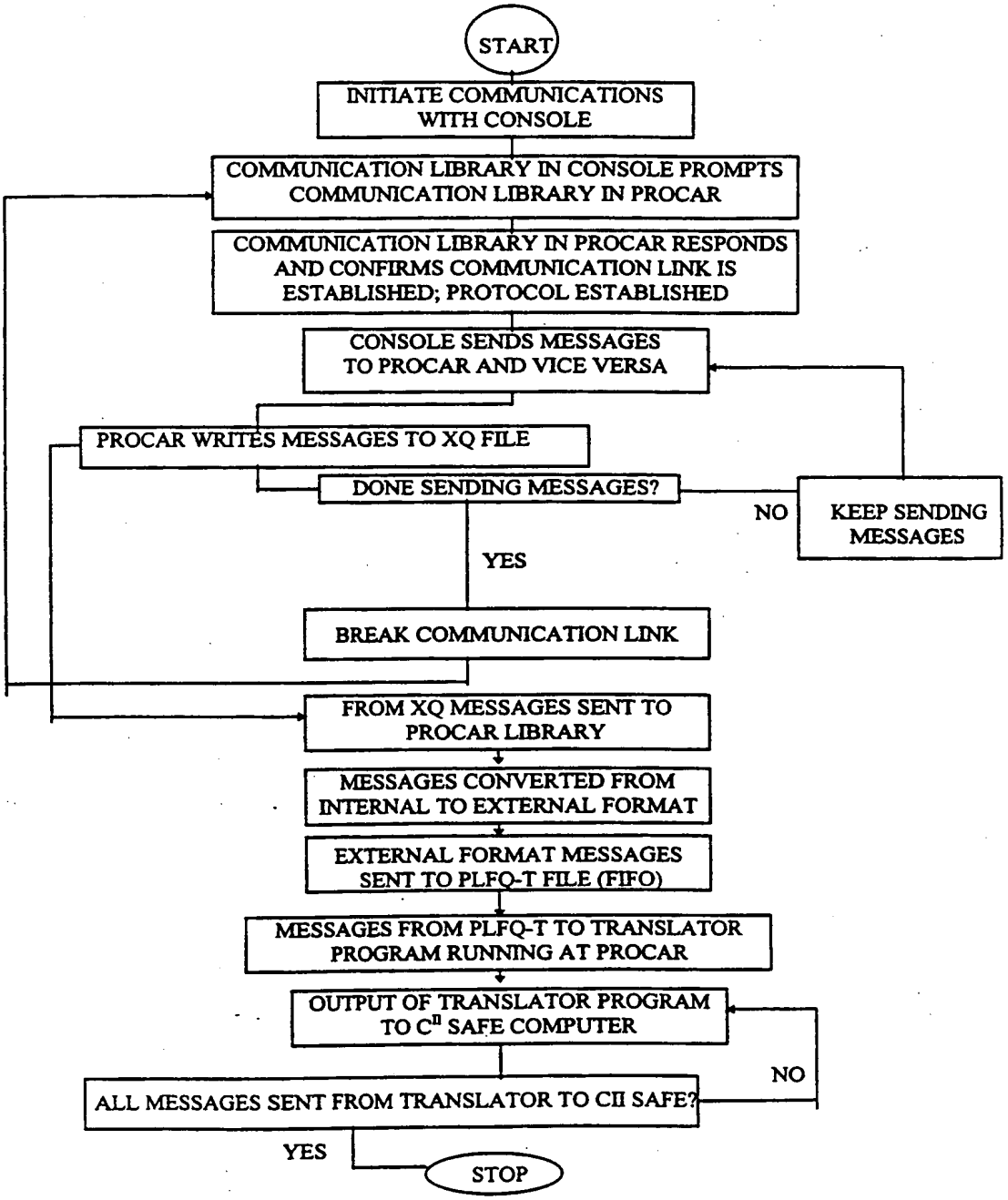


FIG. 2

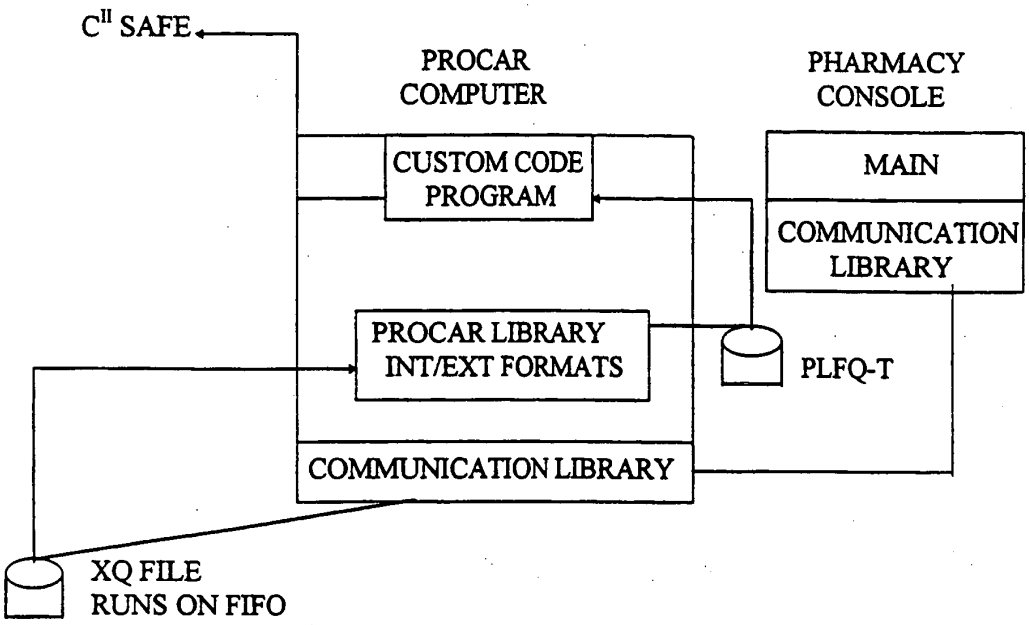


FIG. 3

DRUG: ALPRAZOLAM 0.5MG TAB 1 PACKET
SEND TO: CATH LAB QUANTITY # 20

USE FOR: XANAX 0.5MG TABLET DATE: SCHED: UNIT #:
SHEET EXPIRES: ISSUED BY: TIME:

REF #: 0470194
LINKCODE 103

CONTROLLED DRUG ADMINISTRATION RECORD

	DATE	TIME AM/PM	PATIENT'S FULL NAME	PHYSICIAN'S NAME	DOSE GIVEN	WASTE	BALANCE	ADMINISTERED BY OR WASTE SIG #1	IF WASTE SIG #2
20									
19			Return This To Pharmacy Upon Completion						
18									
17			0470194						
16									
15			DO NOT Place this Document In Patient's Record						
14									
13									
12									
11									
10			Return This To Pharmacy Upon Completion						
9									
8			0470194						
7			DO NOT Place this Document In Patient's Record						
6									
5									
4									
3									
2			Return This To Pharmacy Upon Completion						
1									

0470194

DO NOT Place this Document In Patient's Record

RECORD OF WASTE AND SPOILAGE: (ALL DRUGS NOT ACCOUNTED FOR MUST BE EXPLAINED, SIGNED AND WITNESSED BELOW)

DATE	TIME	LN #	WST	DETAILS	RETURNED	SIG. #1	SIG. #2	REC. RPh

RETURN DOCUMENT TO PHARMACY UPON COMPLETION

CII SAFE Ver 4.0

FIG-4

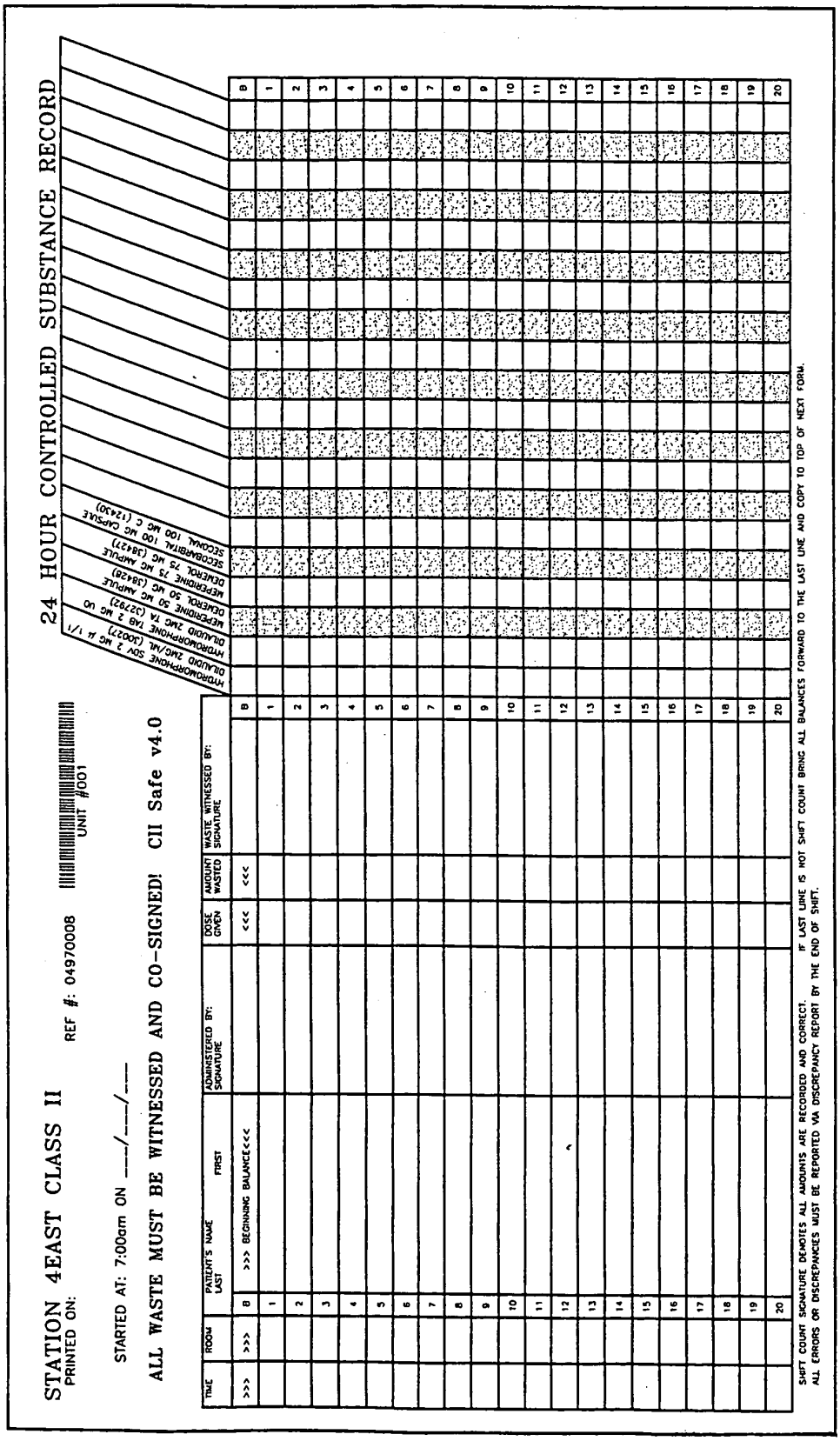


FIG-5

ANESTHESIA CONTROLLED SUBSTANCE SHEET FOR KIT #04970011

KIT WAS USED FROM DATE ____/____/____ TO DATE ____/____/____

ANESTHESIOLOGIST: FILLED BY: AT:

04970011

Record Use in this Format **DOSE/WASTE**

PATIENT'S NAME	ALFENTANIL 5ML AMP	FENTANYL AMP 50MCG/ML 2ML	FENTANYL AMP 50MCG/ML 10ML	MORPHINE (DURAMORPH) 10MG IJ	SUFENTANIL 50MCG INJ 1ML AMP	MIDAZOLAM 1MG/ML INJ 2ML				COSIGNATURE FOR WASTE
M.D.(initial) START COUNT:	5	10	3	3	4		6				
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
ANESTHESIOLOGIST Total Vials Used:											
ANESTHESIOLOGIST ENDING COUNT:											

END COUNT BY PHARMACY (initial): _____

I verify that this sheet is complete and accurate: _____ VERIFIED BY (initial): _____

	1	2	3	4	5	6	7	8	9	
Pharmacy use only Replenish:										
Pharmacy use only New Balance:										

FIG-6

EXPIRE WASTE OR RECALL TRANSACTION RECORD

CIISAFE-NV
Street Address City State Zip Code
Prepared Date: 04-23-1997 Time: 12:16:01

QTY. 10
DRUG: MORPHINE INJ 2MG SYRINGE
REF. W0478

SIG. OF : SAM _____

SIG. OF : HRH _____

MANAGEMENT REVIEW : _____

DATE REMOVED FROM STOCK : 04-23-1997
REASON REMOVED : EXPIRED 03/97
NOTICE!!! Medication was placed in PENDING BIN.

FIG-7A

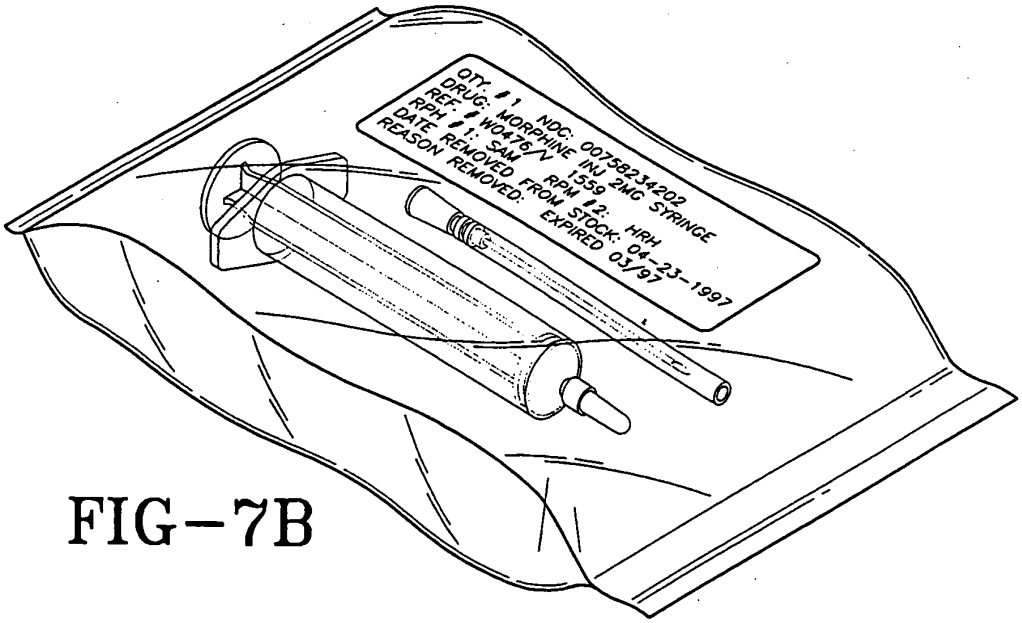


FIG-7B

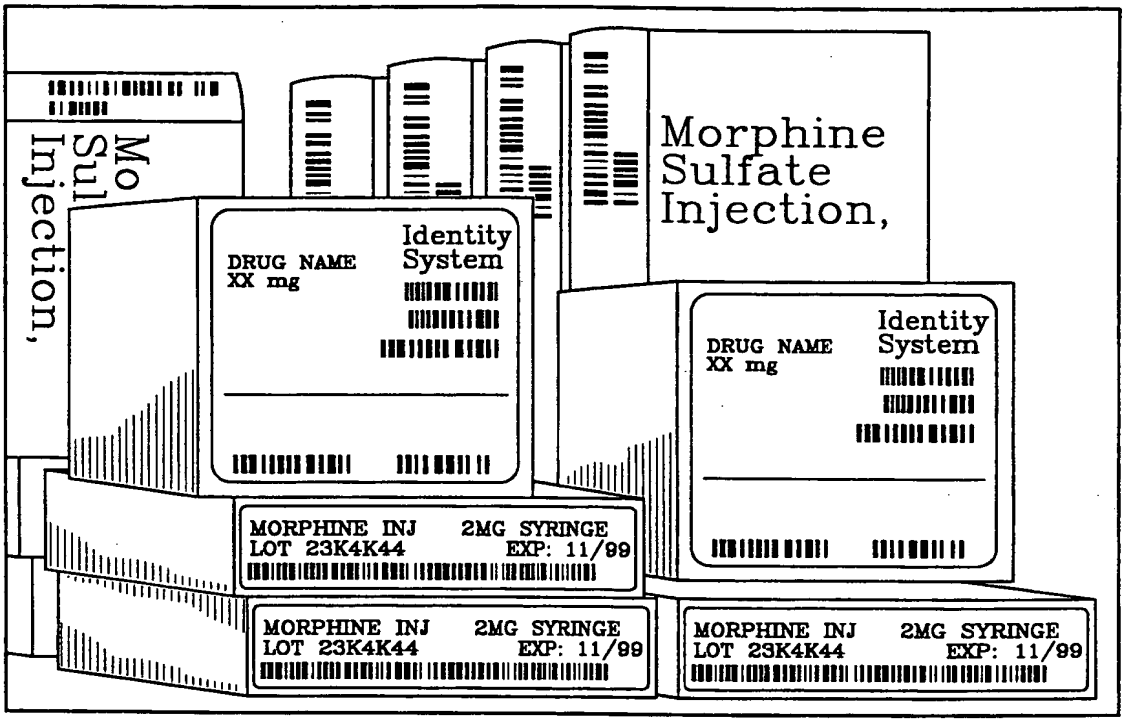


FIG-8A

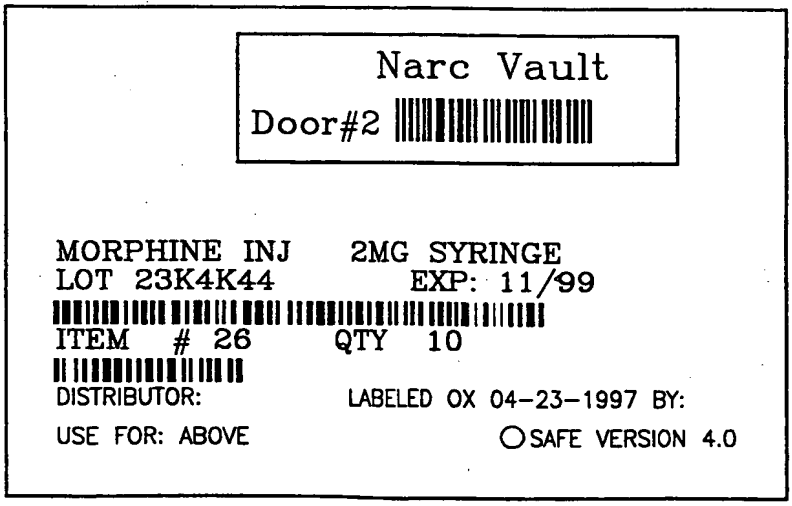


FIG-8B

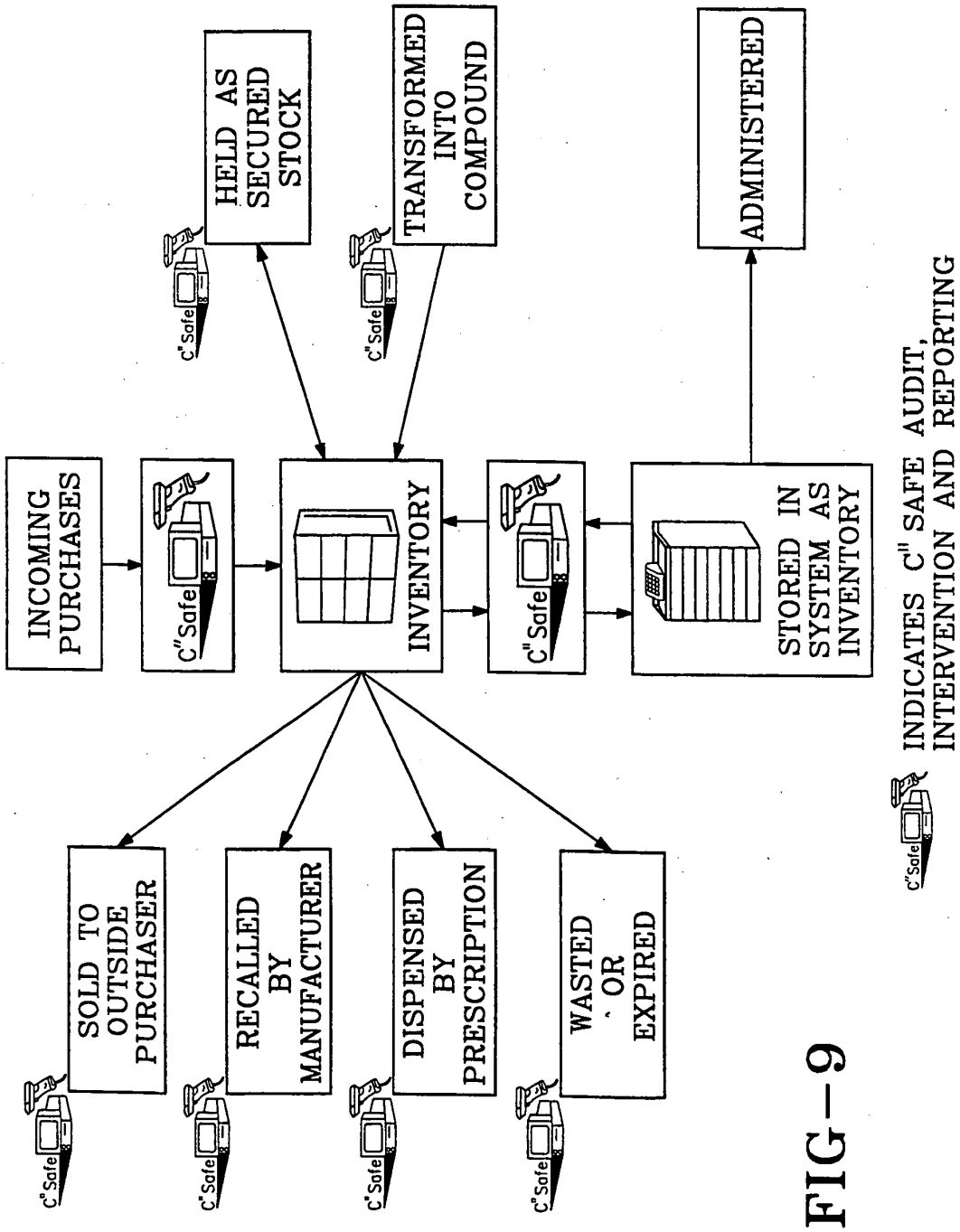


FIG-9

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : G06F 17/60

A3

(11) International Publication Number: WO 98/50840

(43) International Publication Date: 12 November 1998 (12.11.98)

(21) International Application Number: PCT/US98/09490

(22) International Filing Date: 8 May 1998 (08.05.98)

(30) Priority Data:
08/852,958 8 May 1997 (08.05.97) US

(71) Applicant: PINNACLE INTELLECTUAL PROPERTY SERVICES–INTERNATIONAL, INC. [US/US]; Suite 260, 2030 East Flamingo Road, Paradise Valley, NV 89119 (US).

(72) Inventors: KING, James, H.; 1627 Winsome Drive, Escondido, CA 92029 (US). SALOOM, George, T.; 100 South Broadway, Scottsdale, PA 15683 (US).

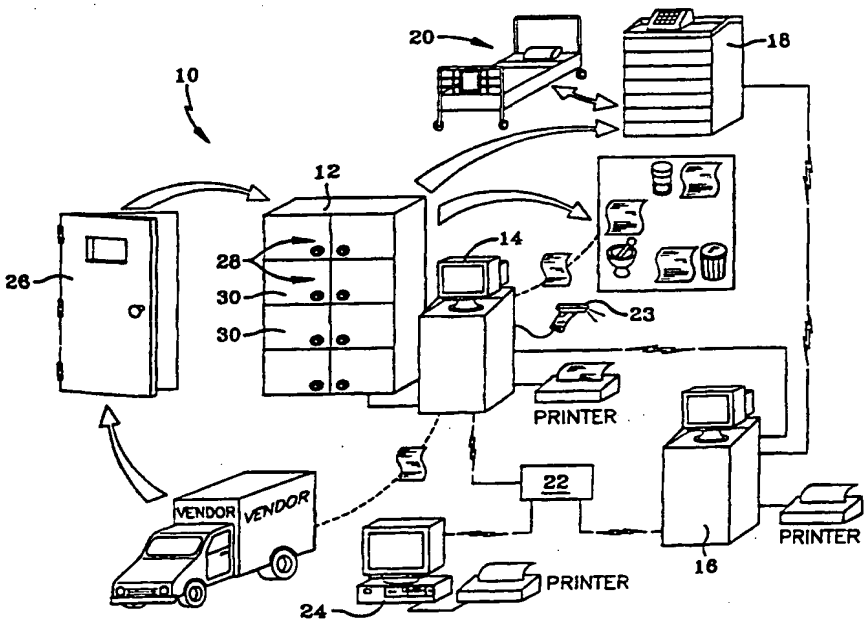
(74) Agent: STEFFENSMEIER, Michael, D.; Cardinal Health, Inc., 5555 Glendon Court, Dublin, OH 43016 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
4 March 1999 (04.03.99)

(54) Title: SYSTEM FOR THE DISTRIBUTION OF NARCOTICS



(57) Abstract

A drug distribution system (10) in which narcotics are tracked from the time they are delivered to the time they are administered to patients are provided in a health care facility. A locked vault (12) having multiple compartments (18) for accessing only through logging onto a computer (14) software system records drugs withdrawn and by whom. The system also provides an inventory and purchase order for restocking purposes.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/09490

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :G06F 17/60
US CL :705/2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/2; 364/479.04, 479.06; 221/2, 10, 92

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,E	US 5,797,515 A (LIFF ET AL.) 25 AUGUST 1998, COLUMN 5, LINE 19 TO COLUMN 6, LINE 67.	1-10
X,P	US 5,713,485 A (LIFF ET AL.) 03 FEBRUARY 1998, COLUMN 4, LINE 54 TO COLUMN 8, LINE 6.	1-10
X	US 4,847,764 A (HALVORSON) 11 JULY 1989, COLUMN 3, LINE 27 TO COLUMN 12, LINE 67.	1-3

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
01 NOVEMBER 1998	14 JAN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FRANTZY POINVIL Joni Hill Telephone No. (703) 305-9779

Form PCT/ISA/210 (second sheet)(July 1992)★